

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
24 July 2003 (24.07.2003)

PCT

(10) International Publication Number
WO 2003/059934 A3

(51) International Patent Classification⁷: C07K 14/00

A. [US/US]; 22400 Rolling Hill Lane, Laytonsville, MD 20882 (US). HASELTINE, William, A. [US/US]; 3053 P Street, N.W., Washington, D.C. 20007 (US).

(21) International Application Number:
PCT/US2002/040892

(74) Agent: WALES, Michele, M.; Human Genome Sciences, Inc., 9410 Key West Avenue, Rockville, MD 20850 (US).

(22) International Filing Date:
23 December 2002 (23.12.2002)

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/341,811 21 December 2001 (21.12.2001) US
60/350,358 24 January 2002 (24.01.2002) US
60/359,370 26 February 2002 (26.02.2002) US
60/360,000 28 February 2002 (28.02.2002) US
60/367,500 27 March 2002 (27.03.2002) US
60/370,227 8 April 2002 (08.04.2002) US
60/378,950 10 May 2002 (10.05.2002) US
60/398,008 24 July 2002 (24.07.2002) US
60/402,131 9 August 2002 (09.08.2002) US
60/402,708 13 August 2002 (13.08.2002) US
60/411,355 18 September 2002 (18.09.2002) US
60/414,984 2 October 2002 (02.10.2002) US
60/417,611 11 October 2002 (11.10.2002) US
60/420,246 23 October 2002 (23.10.2002) US
60/423,623 5 November 2002 (05.11.2002) US

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW); Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM); European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— with sequence listing part of description published separately in electronic form and available upon request from the International Bureau

(71) Applicant (*for all designated States except US*): HUMAN GENOME SCIENCES, INC. [US/US]; 9410 Key West Avenue, Rockville, MD 20850 (US).

(88) Date of publication of the international search report:
26 February 2004

(72) Inventors; and
(75) Inventors/Applicants (*for US only*): ROSEN, Craig

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ALBUMIN FUSION PROTEINS

(57) Abstract: The present invention encompasses albumin fusion proteins. Nucleic acid molecules encoding the albumin fusion proteins of the invention are also encompassed by the invention, as are vectors containing these nucleic acids, host cells transformed with these nucleic acids vectors, and methods of making the albumin fusion proteins of the invention and using these nucleic acids, vectors, and/or host cells. Additionally the present invention encompasses pharmaceutical compositions comprising albumin fusion proteins and methods of treating or preventing diseases, disorders or conditions related to diabetes mellitus using albumin fusion proteins of the invention.

WO 2003/059934 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/40892

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : C07K 14/00 US CL : 530/350 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 530/350 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched none Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST, Dialog, Sequence Search		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	YU et al. A newly identified member of tumor necrosis factor receptor superfamily (TR6) suppresses LIGHT-mediated apoptosis. Journal of Biological Chemistry. 14 May 1999, Vol. 274, No. 20, pages 13733-13736.	1-21
A	US 5,876,969 A (FLEER et al.) 02 March 1999 (02.03.99).	1-21
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search	Date of mailing of the international search report	
12 August 2003 (12.08.2003)	02 SEP 2003	
Name and mailing address of the ISA/US	Authorized officer	
Mail Stop PCT, Attn: ISA/US	Karen Cochran Carlson, Ph.D.	
Commissioner for Patents	Telephone No. 703-308-1235	
P.O. Box 1450		
Alexandria, Virginia 22313-1450		
Facsimile No. (703)305-3230		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/40892

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-21, drawn to fusion protein #1, SEQ ID NO: 70

- Remark on Protest The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US02/40892

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Groups 1-161, claim(s) 1-21, drawn to albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 162-322, claim(s) 22, drawn to method of treating disease via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 323-483, claim(s) 23, drawn to method of treating metabolic disorders via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 484-644, claim(s) 24-33 and 35, drawn to method of treating diabetes via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 645-805, claim(s) 34 and 36, drawn to method of treating obesity via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 806-966, claim(s) 37, drawn to method of extending the shelf life of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

Group 967-1127, claim(s) 38-40, drawn to nucleic acid encoding albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2.

The inventions listed as Groups 1-1127 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the albumen fusion proteins NO:1 differs in structure and function from albumen fusion proteins NO: 2-NO:161 because the attached therapeutic protein is different for each fusion protein as set forth in Table 2. Further, the fusion proteins comprising an amino acid from therapeutic protein X and an amino acid from albumen reads on any peptide sequence and therefore the claimed fusion protein is not novel and does not represent a special technical feature. See, for example, Habermann et al. (US Patent 5,496,924) who teach fusion proteins comprising an Asp-Pro linker, wherein Asp and Pro are considered to be fragments of therapeutic protein X and albumen. Therefore, the groups do not relate to a single general inventive concept.